REMARKS

Claims 1-26 are pending. Support for the amendment to claim 1 appears in the specification at, e.g., page 10, lines 28-30. Support for the amendment to claims 5, 6, 9, 10 and 21-23 specifying the percentage bases appears in the specification at, e.g., page 6, lines 7-8. Support for new claim 26 appears in the specification at, e.g., page 7, lines 18-27. No new matter has been added.

Rejections under 35 U.S.C. §112, first paragraph

Claims 1-25 are rejected for lack of written description. The rejection is traversed.

The claims as amended are drawn to a composition that includes about 1 μg/ml to about 20 mg/ml IL-11, 100 to about 400 mM glycine and 0.5 to about 2.0 % wt/wt cryoprotectant. The claim additionally recites that the IL-11 in the composition shows reduced aggregation as compared to IL-11 stored in a composition with glycine and without the cryoprotectant.

The Examiner states:

> As presently worded, the composition may comprise virtually any one or combinations of "Il-11" as the product is not defined in terms of any activity source, amino acid composition, etc.

Applicants submit that it is not necessary to refer in the claims to an activity, source or amino acid composition for IL-11 in order to satisfy the written description requirement. The Federal Circuit has recently stated that "[t]he 'written description' requirement must be applied in the context of the particular invention and the state of the knowledge." (Capon v. Ether, Fed. Cir. 2005, No. 03-1480, -1481)." In Capon, the Federal Circuit ruled that the Board of Patent Appeals and Interferences erred in holding that generic claims drawn to chimeric antibody genes do not satisfy the written description requirement because the appellants' specifications did not reiterate the structure or formula or chemical name for the nucleotide sequence of the claimed genes. The court observed that "when the prior art includes the nucleotide information, precedent does not set a *per*

se rule that the information must be determined afresh."

Similar to the appellants in Capon, Applicants' invention is not the discovery of IL-11 itself, whose identity and sequence has been known for many years. The currently claimed invention is instead based on new formulations of IL-11. Because one of ordinary skill in the art would readily know what is meant by Applicants' recitation of "IL-11" in the claims, Applicants submit it is not necessary to refer to structural or functional information to comply with the written description requirement. Reconsideration and withdrawal of the rejection for lack of written description is requested.

Claim 1 is separately rejected for lack of written description on the basis that Applicant's previous amendment introduced new matter. The rejection is traversed to the extent it is applied to the claim as amended.

Claim 1 has been amended to recite that IL-11 in the composition shows reduced aggregation as compared to IL-11 stored in a composition with glycine and without said cryoprotectant. Because a composition with this feature is disclosed in the specification at, e.g., Example 1 on pages 9-10, this aspect of the rejection should be withdrawn.

Rejections under 35 U.S.C. §112, second paragraph

Claims 6, 9, 10, and 21-23 are rejected as indefinite for omitting the bases by which the recited percentages are determined. The claims subject to the rejection (as well as claim 5) have been amended to specify that the recited percentages are determined based on wt/wt or wt/vol and Applicants respectfully request that this rejection be withdrawn.

Rejection under 35 U.S.C. §103

Claims 1-25 are rejected as unpatentable over Bennett et al. U.S. Patent No. 5,371,193 ("Bennett") in light of Keith et al., U.S. Patent No. 5,679,339 ("Keith") and Schaefer et al. U.S. Patent No. 6,096,873 ("Schaefer"). The rejection is traversed to the extent it is applied to the claims as amended.

Claim 1, from which the remaining claims subject to the rejection depend, as amended is drawn to a composition that includes 1 μg/ml to about 20 mg/ml IL-11, 100 to about 400 mM glycine and 0.5 to about 2.0 % wt/wt cryoprotectant. The claim additionally recites that the IL-11 in the composition show reduced aggregation as compared to IL-11 stored in a composition with glycine and without the cryoprotectant.

There is no suggestion in the combination of Bennett, Keith and Schaefer of an invention with these features. None of the cited reference suggests that combining IL-11, glycine and a cryoprotectant in the recited concentrations would result in an IL-11-containing composition with reduced aggregation, as recited by the claims. Nor is there a reasonable expectation of success in making a composition with the recited properties.

Bennett is cited for describing pharmaceutical compositions that include IL-11. As noted by the Examiner, it is silent on the remaining components of the claimed combination. Keith discloses compositions that include IL-11 and sucrose (a cryoprotectant), and compositions that include IL-11 and glycine. However, this reference lacks any suggestion for making a composition that includes all of IL-11, sucrose, and glycine. The reference also lacks any suggestion that such a composition would have reduced aggregation properties.

Schaefer fails to overcome the deficiencies of Bennett and Keith. Schaefer does not disclose IL-11 but is cited instead for describing pharmaceutical formulations of gamma-heregulin that

include low molecular weight proteins less than 10 amino acids, and cryoprotectants, and surfactants. Applicants respectfully disagree with the Examiner's assertion that the artisan would substitute IL-11 for gamma-heregulin in Schaefer's pharmaceutical compositions. The amino acid sequences of IL-11 and gamma-heregulin, which is nearly four times larger than IL-11, show no significant homology.[1] One of ordinary skill in the art would presume that these two proteins would, more likely than not, interact differentially with the components listed above. For example, the instant specification teaches, as explained above, that IL-11 tends to form soluble high molecular weight aggregates, which interferes with product quality and effectiveness. There is no teaching in Schaefer that gamma-heregulin has the same technical problems. Thus, Applicants submit that one of ordinary skill in the art would not expect that replacing gamma-heregulin in the formulations of Schaefer with IL-11 as described in Bennett or Keith would be successful.

[1] See Exhibit A, which is a comparison of the primary amino acid structure of IL-11 and gamma-heregulin.

On the basis of the foregoing amendment and remarks, Applicants respectfully submit that the pending claims are in condition for allowance. If there are any questions regarding this amendment and/or these remarks, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

The Commissioner is authorized to charge any additional fees that may be due, or to credit any overpayment, to the undersigned's account, Deposit Account No. 50-0311, Reference No. 22058-531CON.

Respectfully submitted,

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